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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,759

03/10/2006

Kjell Undheim

HLB-0010

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CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

07/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,759	Applicant(s) UNDHEIM ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 10 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

The abstract of the disclosure is objected to because it has not been presented in the proper domestic form. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: On page 1, the specification fails to state that this case is a 371 Of PCT/GB03/05659. The structural formula (I) on page 10 of the specification is not clear.

Appropriate correction is required.

Claim 6 is objected to because of the following informalities: Formula (V) is incomplete. Appropriate correction is required.

Claims 1-5, 7, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of formula (II), (III), (IV) and (V) as set forth on page 11 of the specification, does not reasonably provide enablement for macrolides in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

(A) The breadth of the claims.

The claims encompass any macrolides or macrolide analogs. Note that on page 1, second paragraph, it is stated that "macrolide antibiotics are a large class of compound".

(B) The amount of direction provided by the inventor.

The inventor has not provided any direction of how to chose specific macrolides other than erythromycins of formula (II), (III), (IV) and (V).

(C) The existence of working examples.

The working examples are limited to erythromycins of formulas (II), (III), (IV) and (V).

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which macrolides will have the desired antibacterial activity, it would take an enormous amount of trial and error to test various macrolides.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means, that, based on the evidence regarding each of the factors below, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

(A) The breadth of the claims.

The terms "aryl" and "heteroaryl" are not limited to any number of rings or to any number or kind of heteroatoms.

(B) The state of the prior art.

Macrolides having aryl or heteroaryl substituents at the 10-position are not known in the prior art.

(C) The amount of direction provided by the inventor.

The inventor has not provided any direction of how to choose specific aryls or heteroaryls.

(D) The existence of working examples.

No examples of specific aryls or heteroaryls are present in the specification.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which specific compounds encompassed by the present claims will have the desired antibacterial activity, it would take an enormous amount of trial and error to test a large number of the claimed compounds.

Claims 1-5, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "comprises" (claim 1) renders the claims indefinite in that it leaves the structural formula of the claimed compound open-ended i.e. the metes and bounds of the claimed invention cannot be determined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al (WO 98/51695).

Katz et al disclose the claimed antibacterial 10-desmethyl macrolides having hydrogen, ethyl or hydroxy group at the 10-position

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623